HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service T2097M

Food and Drug Administration
New Orleans District
Southeast Region
4298 Elysian Fields Avenue
New Orleans, Louisiana 70122-3896

Telephone: 504-589-6341
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October 2, 1998

WARNING LETTER NO. 99-NOL-02

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Eric O. Nguyen, Owner
C & J Seafood and Crab Company, Inc.
116 North Hollywood Road
Houma, Louisiana 70364-2806

Dear Mr. Nguyen:

During an inspection of C & J Seafood and Crab Company, Inc., 116 North Hollywood Road, Houma, Louisiana, conducted on September 21-23, 1998, our investigator documented numerous insanitary conditions in your picked crabmeat operation. This causes your finished product, picked crabmeat, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act.

Objectionable insanitary conditions noted included:

1. Cooked crabs in perforated metal crates and backed crabs in perforated plastic baskets, resting in water on the backing room floor which is subject to heavy foot traffic from outside areas;

2. On one occasion, an employee picked up two crabs from the backing room floor, then returned them to production;

3. Water from the chute washer splashing from the backing room floor onto cooked crabs in baskets;

4. On one occasion, an employee entered the plant from outside, then contacted cooked crabs in a plastic basket with the bottom of his rubber boot;

5. An employee routinely handled live crabs, the hoist control, then contacted cooked crabs without washing or sanitizing his hands;

6. Two employees entered the plant and began backing crabs without washing or sanitizing their hands;

7. Numerous live flies outside and inside the plant in direct contact with cooked crabs;

8. Cooked crabs protruding from baskets in contact with the dirty, encrusted cooler door, a rubber hose on the chute washer, and the walls of the cooler;

9. Employees routinely handled the dirty encrusted cooler door handle, then contacted cooked crabs without washing or sanitizing their hands;

10. Perforated plastic baskets used to hold cooked crabs had dirty, encrusted surfaces; and,

11. Numerous other improper employee practices which could lead to contamination of the firms finished product.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the steps taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action can not be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Richard D. Debo, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana, 70122-3896, telephone number (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Mr. Debo.

Additionally, this inspection was conducted to determine compliance with FDA's seafood processing regulations (21 CFR 123) and the Good Manufacturing Practices requirements for foods (21 CFR 110).

The seafood processing regulations, which became effective on December 18, 1997, require you to implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operations to eliminate or minimize the likelihood the identified hazards will occur. These are the kinds of measures prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have fully operating HACCP systems advise us that they benefit from it in several

ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the inspection, of your crab picking plant, the FDA investigator observed shortcomings in your system that, upon preliminary review, appear to be deviations from the principles of HACCP and the significant requirements of the program. The FDA investigator also provided you with a copy of the Domestic Seafood HACCP Report (form FDA-3501) and the FDA-483 which presents his/her evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. The observations of concern to us are as follows:

- Failure to identify the backing step as a CCP for time/temperature control of the significant hazard pathogen growth as required under 21 CFR Part 123.6(c)(2). The critical control point begins when a cooked ready-to-eat product is further handled or contacts surfaces that were not heated along with the product. At this point, time above a critical temperature becomes a critical limit and must be monitored, unless it is a very short time, e.g. 30 minutes;

- Failure to adequately monitor cook times, a CCP, to control the significant hazard pathogen survival, as required under CFR Part 123.6(b), in that production records from December 17, 1997 to September 21, 1998 (27 production days), revealed cook temperatures of less than 210°F, the critical limit for cook temperature;

- Failure to take corrective action regarding inadequate cook temperatures, as noted above, as required under 21 CFR Part 123.7(a); and,

- Failure to provide documentation regarding the adequacy of the cook step critical limits, a CCP to control the significant hazard pathogen survival as required under 21 CFR Part 123.6(c)(3).

Objectionable equipment and insanitary conditions as listed on Form FDA-483 and Form FDA-3501 are an indication that sanitation monitoring [21 CFR 123.11(b)] at the firm is inadequate. Calling your attention to the objectionable insanitary conditions in this letter is in the interest of having your firm improve its sanitation program consistent with the HACCP principles. A failure to make appropriate corrections could cause your HACCP processing system to be found unacceptable during a future FDA inspection. The noted objectionable insanitary conditions are listed in paragraph two (2) of this letter.

We encourage you to make the necessary improvements as soon as possible. However, if you disagree with FDA's preliminary assessment of deviations from HACCP Regulations, you should explain how your system identifies hazards and implements controls in a manner the agency should regard as complying with the regulations. We understand that HACCP systems may be uniquely tailored to meet the circumstances of the individual processor and there may be more than one right way to control hazards.

In either case, it is essential that you respond to this office on this matter within 30 working days of the receipt of this letter. Upon receipt of a timely response, we will work with you to resolve any outstanding issues associated with your HACCP system. If we do not hear from you, or if

your response is inadequate, we will assume our preliminary conclusions are correct and we will schedule a follow-up inspection for the immediate future.

Your reply, relating to these concerns, should be directed to the Food and Drug Administration, Attention: Richard D. Debo, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896. If you have questions regarding the implementation of the HACCP regulation or the application of HACCP to your specific process, you may contact Mr. Debo at (504) 589-7166 for answers and/or direction towards guidance and sources of training in achieving compliance.

Sincerely,

James E. Gamet
District Director
New Orleans District Office

Enclosure: FDA-483

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